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EXAMINER

CROW, ROBERT THOMAS

ART UNIT PAPER NUMBER

1634

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/722,290	Applicant(s) HAHN ET AL.	
	Examiner Robert T. Crow	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 10 August 2006 in which claims 1, 4, 5, 7, 11, 18, were amended, claims 15-17 were canceled, and new claims 23-25 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 1-14 and 23-25 are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 1-5, 9, 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schembri (U.S. Patent No. 6,186,659 B1, issued 13 February 2001) in view of Chung et al (U.S. Patent Application Publication No. US 2003/0123322 A1, published 3 July 2003).

Regarding claim 1, Schembri teaches a microarray hybridization device which comprises: a flat substrate having a surface to which a microarray of reactive moieties can be attached; namely, an oligonucleotide array on the substrate surface (column 5, lines 20-47 and column 5, line 60-column 6, line 24). Schembri also teaches a rectangular substrate (column 5, lines 7-9), and liquid barrier means juxtaposed with said surface to create a chamber having an interior wall surface; namely, seal 15 of Figure 4 which is attached to the outer periphery of the substrate to create a chamber for sample fluids (column 6, lines 25-27). Since the substrate is rectangular, the seal on the outer periphery would constitute four walls having an interior wall surface facing the inside of the chamber. Schembri also teaches the array is in the chamber (column 5, lines 20-47). Schembri teaches the device has a cover; namely, the second substrate 11 of Figure 4 (column 6, lines 30-34). Figure 2 of Schembri also shows seal 15, which is the liquid barrier means, as generally perpendicular to the substrate surface.

Schembri teaches said barrier means having inwardly facing surfaces which border said chamber (i.e., the walls of the chamber) and that a bubble in the chamber is used to facilitate mixing of the liquid target solution (e.g., mixing is accomplished via movement of the bubbles; column 5, lines 50-56). While Schembri also teaches mechanical sources for forming bubbles on the inner surfaces of the substrate (column 5, lines 18-21), Schembri does not teach barrier means with a plurality of bubble-fracturing elements.

However, Chung et al teach a fluidic apparatus (Abstract) for use in screening nucleic acids (paragraph 0032). Chung et al teach a chamber of the device having a plurality of baffles that extend laterally into the chamber by spanning the substrate (paragraph 0052) and by having a thickness that extends laterally into the chamber (Figure 5) wherein the baffles have sharp edges (i.e., the corners of the baffles; Figure 5). Therefore, the baffles of Chung et al meet the

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limitation of barrier means for bubble-fracturing elements that extend laterally in the chamber, defined on page 9 of the instant Specification as structures that extend into the reaction chamber (e.g., span a substrate as taught by Chung et al; paragraph 0052), and have sharp edges (e.g., the corners of the baffles as taught by Chung et al; Figure 5).

While Chung et al do not specifically teach the baffles on the walls, the rearrangement of parts within a device is obvious when the arrangement does not specifically modify the operation of the device. Chung et al also teach the added benefit that the baffles facilitate operation of the fluidic apparatus (paragraph 0048).

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." Therefore, the various uses recited in claim (e.g., fracturing of the bubbles) fail to define additional structural elements to the device of claim 1. Because Chung et al teach the structural limitations of the bubble fracturing elements of claim 1 (e.g., baffles having corners), the claim is obvious over the teachings of Schembri in view of Chung et al.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the device as taught by Schembri with the plurality of bubble-fracturing elements (i.e., baffles) as taught by Chung et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have facilitated operation of the fluidic apparatus as explicitly taught by Chung et al (paragraph 0048).

Regarding claim 2, the device of claim 1 is discussed above. Schembri also teach the device wherein the cover is flat (column 11, lines 53-55) and is spaced uniformly from said surface by said barrier means; namely, the cover must be parallel to the plane of the substrate to avoid artificial gradients (column 3, lines 25-31).

Regarding claim 3, the device of claim 3 is discussed above. Chung et al also teach the device wherein the cover is substantially rigid and transparent (e.g., glass; paragraph 0038).

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Regarding claim 4, the device of claim 2 is discussed above. Schembri also teaches the device wherein said barrier means has a height such as to space said cover about between 0.2 and about 2 mm for said surface; namely, the chamber is about 0.5 mm high (column 5, lines 47-50).

Regarding claim 5, the device of claim 2 is discussed above. Schembri et al teach the device is rectangular, and therefore has four walls formed by the seal 15 of Figure 4 attached to the outer periphery of the substrate (column 6, lines 25-27). Chung et al teach the baffles include sharp edges (e.g., corners of baffles) that are aligned substantially perpendicular to said surface (paragraph 0052 and Figures 3 and 5). As stated above, while Chung et al do not specifically teach the baffles on the walls, the rearrangement of parts within a device is obvious when the arrangement does not specifically modify the operation of the device. Chung teaches the edges of the baffles are spaced apart by pockets (i.e., gaps) and are perpendicular to the surface of the substrate (paragraph 0052 and Figures 3 and 5).

As stated above, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." Therefore, the various uses recited in claim (e.g., fracturing of bubbles) fail to define additional structural elements to the device of claim 5. Because Chung et al teach the structural limitations of the bubble fracturing elements of claim 5, the claim is obvious over the teachings of Schembri in view of Chung et al.

Regarding claim 9, the device of claim 2 is discussed above. Schembri et al teach the device is made from the hydrophobic material fused silica (column 5, lines 1-7).

Regarding claim 11, Schembri teaches a microarray hybridization device which comprises:

a flat substrate having an upper surface and a microarray of reactive moieties attached to said upper surface; namely, an oligonucleotide array on the substrate surface (column 5, lines 20-47). Schembri also teaches a liquid perimeter barrier juxtaposed with said surface to create a chamber having an interior wall surface; namely, seal 15 of Figure 4 which is attached to the outer periphery of the substrate to create a chamber for sample fluids (column 6, lines 25-27).

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Since the substrate is rectangular, the seal on the outer periphery would constitute four walls having an interior wall surface facing the inside of the chamber. Schembri also teaches the array is in the chamber (column 5, lines 20-47). Schembri teaches the device has a cover; namely, the second substrate 11 of Figure 4 (column 6, lines 30-34). Figure 2 of Schembri also shows seal 15, which is the liquid perimeter barrier, as generally perpendicular to the substrate surface.

Schembri teaches said barrier means having inwardly facing surfaces which border said chamber (i.e., the walls of the chamber) and that a bubble in the chamber is used to facilitate mixing of the liquid target solution (e.g., mixing is accomplished via movement of the bubble; column 5, lines 50-56). While Schembri also teaches mechanical sources for forming bubbles on the inner surfaces of the substrate (column 5, lines 18-21), Schembri does not teach barrier means with a plurality of bubble-fracturing elements.

However, Chung et al teach a fluidic apparatus (Abstract) for use in screening nucleic acids (paragraph 0032). Chung et al teach a chamber of the device having a plurality of baffles that extend laterally into the chamber by spanning the substrate (paragraph 0052) and by having a thickness that extends laterally into the chamber (Figure 5) wherein the baffles have sharp edges (i.e., the corners of the baffles; Figure 5). Therefore, the baffles of Chung et al meet the limitation of barrier means for bubble-fracturing elements that extend laterally in the chamber, defined on page 9 of the instant Specification as structures that extend into the reaction chamber (e.g., span a substrate as taught by Chung et al; paragraph 0052), and have sharp edges (e.g., the corners of the baffles as taught by Chung et al; Figure 5).

While Chung et al do not specifically teach the baffles on the walls, the rearrangement of parts within a device is obvious when the arrangement does not specifically modify the operation of the device. Chung et al also teach the added benefit that the baffles facilitate operation of the fluidic apparatus (paragraph 0048).

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather

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than function.” Therefore, the various uses recited in claim (e.g., fracturing of the bubbles) fail to define additional structural elements to the device of claim 11. Because Chung et al teach the structural limitations of the bubble fracturing elements of claim 11 (e.g., baffles having corners), the claim is obvious over the teachings of Schembri in view of Chung et al.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the device as taught by Schembri with the plurality of bubble-fracturing elements (i.e., baffles) as taught by Chung et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have facilitated operation of the fluidic apparatus as explicitly taught by Chung et al (paragraph 0048).

Regarding claim 12, the device of claim 11 is discussed above. Schembri also teaches the device wherein the cover is flat (column 11, lines 53-55) and is spaced uniformly from said surface by said barrier means (i.e., the cover must be parallel to the plane of the substrate to avoid artificial gradients; column 3, lines 25-31). Schembri teaches the device wherein said barrier means has a height such as to space said cover about 0.2 and about 2 mm for said surface (e.g., the chamber is about 0.5 mm high; column 5, lines 47-50). Chung et al teach the device wherein the cover is substantially rigid and transparent (e.g., glass; paragraph 0038).

Regarding claim 13, the device of claim 12 is discussed above. Schembri et al teach the device is rectangular, and therefore has four walls formed by the seal 15 of Figure 4 attached to the outer periphery of the substrate (column 6, lines 25-27). Chung et al teach the baffles include sharp edges (e.g., the corners of the baffles) that are aligned substantially perpendicular to said surface (paragraph 0052 and Figures 3 and 5). As stated above, while Chung et al do not specifically teach the baffles on the walls, the rearrangement of parts within a device is obvious when the arrangement does not specifically modify the operation of the device. Chung teaches the edges of the baffles are spaced apart by pockets (i.e., gaps) and are perpendicular to the surface of the substrate (paragraph 0052 and Figures 3 and 5).

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As stated above, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." Therefore, the various uses recited in claim (e.g., fracturing of bubbles) fail to define additional structural elements to the device of claim 13. Because Chung et al teach the structural limitations of the bubble fracturing elements of claim 13 (e.g., the corners of the baffles), the claim is obvious over the teachings of Schembri in view of Chung et al.

5. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schembri (U.S. Patent No. 6,186,659 B1, issued 13 February 2001) and Chung et al (U.S. Patent Application Publication No. US 2003/0123322 A1, published 3 July 2003) as applied to claim 5 above, and further in view of del Valle P. et al (U.S. Patent No. 4,750,556, issued 14 June 1988).

Regarding claim 6, the device of claim 5 is discussed above. Chung et al also teach the bubble-fracturing elements are disposed opposite to one another; namely, the baffles separated from both the substrate and the cover plate (paragraph 52) and are on opposite sides of the center of the chamber (Figure 3). Chung et al teach the baffles include sharp edges (e.g., corners of baffles) that project into the chamber (paragraph 0052 and Figures 3 and 5). As stated above, while Chung et al do not specifically teach the baffles on the walls, the rearrangement of parts within a device is obvious when the arrangement does not specifically modify the operation of the device. Chung teaches the edges of the baffles are spaced apart by pockets (i.e., gaps) and are perpendicular to the surface of the substrate (paragraph 0052 and Figures 3 and 5).

Neither Schembri nor Chung et al teach triangular baffles.

However, del Valle P. et al teach a reactor apparatus having a reactor vessel with triangular baffles with the added advantage that the triangular baffles allow optimum regulation of reaction conditions and increase reactor productivity (Abstract).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the device as taught by Schembri and Chung et al

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with the triangular baffles as taught by del Valle P. et al with a reasonable expectation of success.

The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in optimum regulation of reaction conditions and increased reactor productivity as explicitly taught by del Valle P. (Abstract).

Regarding claim 7, the device of claim 6 is discussed above. Schembri teaches the substrate is rectangular and distinguishes the rectangle from a square (column 5, lines 5-10); therefore, there are two shorter walls and two longer walls. While Chung et al do not specifically teach the baffles on the shorter walls, the rearrangement of parts within a device is obvious when the arrangement does not specifically modify the operation of the device.

Regarding claim 8, the device of claim 7 is discussed above. Chung et al also teach the baffles are aligned so as to project in the direction from which bubbles in the target solution in said chamber will normally approach the respective wall with the device is moved; namely, the baffles are aligned along the direction of fluid flow between the inlet and outlet ports 24a and 24b of Figure 3.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schembri (U.S. Patent No. 6,186,659 B1, issued 13 February 2001) and Chung et al (U.S. Patent Application Publication No. US 2003/0123322 A1, published 3 July 2003) as applied to claim 2 above, and further in view of Bedingham et al (U.S. Patent Publication Application No US 2002/0047003, published 25 April 2002).

Regarding claim 10, the device of claim 2 is discussed above. While Schembri teaches the device wherein the chamber is made from hydrophobic materials (i.e., fused silica; column 5, lines 1-7), neither Schembri nor Chung et al teach opaque materials.

However, Bedingham et al teach a fluidic device (paragraph 0240) for handling nucleic acids (paragraph 0027) wherein the device (i.e., including the cover) is made of opaque materials

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with the added benefit that the chambers of the device are substantially shielded from energy that is detrimental to the desired reactions (paragraph 0153).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the device as taught by Schembri and Chung et al with the opaque cover taught by Bedingham et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in the chambers of the device being substantially shielded from energy that is detrimental to the desired reactions as explicitly taught by Bedingham et al (paragraph 0153).

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schembri (U.S. Patent No. 6,186,659 B1, issued 13 February 2001) and Chung et al (U.S. Patent Application Publication No. US 2003/0123322 A1, published 3 July 2003) as applied to claim 12 above, and further in view of Taylor et al (PCT International Publication Number WO 99/36576, published 22 July 1999).

Regarding claim 14, the device of claim 12 is discussed above. Schembri also teaches said cover includes at least one filling port through which said liquid target solution can be applied into said chamber (column 12, lines 3-5 and Figure 2) and wherein said microarray includes a plurality of spots which are attached to said upper surface and extend upward (e.g., spots are on the surface and have a thickness; column 2, lines 11-25 and Figure 9).

Both Schembri and Chung et al are silent with respect to the thickness of the spots.

However, Taylor et al teach intelligent gel pad arrays (Abstract) on a support for sequencing by hybridization wherein the gel pads carry reactive moieties (e.g., nucleic acids are immobilized in the pads; page 1, lines 34-36) have a thickness of about 20 microns (page 19, lines 19-22) with the added advantage that intelligent gel pads produce signals that are detected and correlated with analyte concentration (page 24, lines 3-11).

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It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the method of Schembri and Chung et al with the intelligent gel pads as taught by Taylor et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because such a modification would have resulted in an array that produces signals that are detected and correlated with analyte concentration as explicitly taught by Taylor et al (page 24, lines 3-11).

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schembri (U.S. Patent No. 6,186,659 B1, issued 13 February 2001) in view of Chung et al (U.S. Patent Application Publication No. US 2003/0123322 A1, published 3 July 2003) and in view of Anderson et al (U.S. Patent No. 5,922,591, issued 13 July 1999).

Regarding claim 23, Schembri teaches a microarray hybridization device which comprises:

a flat substrate having a surface to which a microarray of reactive moieties can be attached; namely, an oligonucleotide array on the substrate surface (column 5, lines 20-47 and column 5, line 60-column 6, line 24). Schembri also teaches a rectangular array of RNA (e.g., Example 2). Because the RNA probes have a length situated above the flat (i.e., two-dimensional) substrate to which the array is attached, the RNA probe array is interpreted as being an array of reactive moieties in 3D spots attached to said upper surface.

Schembri also teaches a rectangular substrate (column 5, lines 7-9), and a rectangular liquid perimeter barrier juxtaposed with said surface to create a chamber having an interior wall surface; namely, seal 15 of Figure 4 which is attached to the outer periphery of the substrate to create a chamber for sample fluids (column 6, lines 25-27). Since the substrate is rectangular, the seal on the outer periphery would constitute four walls having an interior wall surface facing the inside of the chamber. Schembri also teaches the array is in the chamber (column 5, lines 20-47). Schembri teaches the device has a flat cover; namely, the second substrate 11 of Figure 4 (column

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6, lines 30-34). The cover has a filling port (column 7, lines 10-15). Figure 2 of Schembri also shows seal 15, which is the rectangular liquid perimeter barrier, as generally perpendicular to the substrate surface.

Schembri teaches said barrier means having inwardly facing surfaces which border said chamber (i.e., the walls of the chamber) and that a bubble in the chamber is used to facilitate mixing of the liquid target solution (e.g., mixing is accomplished via movement of the bubble; column 5, lines 50-56). While Schembri also teaches mechanical sources for forming bubbles on the inner surfaces of the substrate (column 5, lines 18-21), Schembri does not teach barrier means with a plurality of bubble-fracturing elements.

However, Chung et al teach a fluidic apparatus (Abstract) for use in screening nucleic acids (paragraph 0032). Chung et al teach a chamber of the device having a plurality of baffles that extend laterally into the chamber by spanning the substrate (paragraph 0052) and by having a thickness that extends laterally into the chamber (Figure 5) wherein the baffles have sharp edges (i.e., the corners of the baffles; Figure 5). Therefore, the baffles of Chung et al meet the limitation of barrier means for bubble-fracturing elements that extend laterally in the chamber, defined on page 9 of the instant Specification as structures that extend into the reaction chamber (e.g., span a substrate as taught by Chung et al; paragraph 0052), and have sharp edges (e.g., the corners of the baffles as taught by Chung et al; Figure 5).

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." Therefore, the various uses recited in claim (e.g., fracturing of the bubbles) fail to define additional structural elements to the device of claim 23. Because Chung et al teach the structural limitations of the bubble fracturing elements of claim 23, the claim is obvious over the teachings of Schembri in view of Chung et al.

While Chung et al do not specifically teach the baffles on the walls, the rearrangement of parts within a device is obvious when the arrangement does not specifically modify the operation

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of the device. Chung et al also teach the added benefit that the baffles facilitate operation of the fluidic apparatus (paragraph 0048).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the device as taught by Schembri with the plurality of bubble-fracturing elements (i.e., baffles) as taught by Chung et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have facilitated operation of the fluidic apparatus as explicitly taught by Chung et al (paragraph 0048).

While Schembri teaches a filling port (column 7, lines 10-15), and while Chung et al teach inlet port 24a (paragraph 0050 and Figure 3), neither Schembri nor Chung et al teach a means for sealing the port.

However, Anderson et al teach a miniaturized integrated nucleic acid diagnostic device (Abstract) comprising a chamber and a polymer array therein (column 2, lines 20-39). Anderson et al also teach the device has sealable openings for injecting the sample; e.g., a sealable valve, which is a means for sealing the filling port. Anderson et al also teach the advantage that sealable valves reduce the threat of leakage during and after sample injection (column 5, line 66-column 6, line 4).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the device comprising inlet ports as taught by Schembri in view of Chung et al with the means for sealing the port as taught by Anderson et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a reduction of the threat of leakage during and after sample injection as explicitly taught by Anderson et al (column 5, line 66-column 6, line 4).

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9. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schembri (U.S. Patent No. 6,186,659 B1, issued 13 February 2001) in view of Chung et al (U.S. Patent Application Publication No. US 2003/0123322 A1, published 3 July 2003) and in view of Anderson et al (U.S. Patent No. 5,922,591, issued 13 July 1999) as applied to claim 23 above, and further in view of del Valle P. et al (U.S. Patent No. 4,750,556, issued 14 June 1988).

Regarding claim 24, the device of claim 23 is discussed above. Chung et al also teach the bubble-fracturing elements are disposed opposite to one another; namely, the baffles separated from both the substrate and the cover plate (paragraph 52) and are on opposite sides of the center of the chamber (Figure 3). Chung et al teach the baffles include sharp edges (e.g., corners of baffles) that project into the chamber (paragraph 0052 and Figures 3 and 5). As stated above, while Chung et al do not specifically teach the baffles on the walls, the rearrangement of parts within a device is obvious when the arrangement does not specifically modify the operation of the device. Chung teaches the edges of the baffles are spaced apart by pockets (i.e., gaps) and are perpendicular to the surface of the substrate (paragraph 0052 and Figures 3 and 5).

Neither Schembri, Chung et al, nor Anderson et al teach triangular baffles.

However, del Valle P. et al teach a reactor apparatus having a reactor vessel with triangular baffles with the added advantage that the triangular baffles allow optimum regulation of reaction conditions and increase reactor productivity (Abstract).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the device as taught by Schembri in view of Chung et al in view of Anderson et al with the triangular baffles as taught by del Valle P. et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in optimum regulation of reaction conditions and increased reactor productivity as explicitly taught by del Valle P. (Abstract).

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10. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schembri (U.S. Patent No. 6,186,659 B1, issued 13 February 2001) in view of Chung et al (U.S. Patent Application Publication No. US 2003/0123322 A1, published 3 July 2003), Anderson et al (U.S. Patent No. 5,922,591, issued 13 July 1999), and del Valle P. et al as applied to claim 24 above, and further in view of Taylor et al (PCT International Publication Number WO 99/36576, published 22 July 1999).

Regarding claim 25, the device of claim 24 is discussed above. While Chung et al do not specifically teach the baffles on the shorter walls, the rearrangement of parts within a device is obvious when the arrangement does not specifically modify the operation of the device.

As stated above, Schembri also teaches a rectangular array of RNA (e.g., Example 2). Because the RNA probes have a length situated above the flat (i.e., two-dimensional) substrate to which the array is attached, the RNA probe array is interpreted as being an array of reactive moieties in 3D spots attached to said upper surface.

Schembri, Chung et al, Anderson et al, and del Valle P. et al are silent with respect to the thickness of the spots.

However, Taylor et al teach intelligent gel pad arrays (Abstract) on a support for sequencing by hybridization wherein the gel pads carry reactive moieties (e.g., nucleic acids are immobilized in the pads; page 1, lines 34-36) have a thickness of about 20 microns (page 19, lines 19-22) with the added advantage that intelligent gel pads produce signals that are detected and correlated with analyte concentration (page 24, lines 3-11).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the method of Schembri in view of Chung et al, Anderson et al, and del Valle P. et al with the intelligent gel pads as taught by Taylor et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because such a modification would have resulted in an array that produces

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signals that are detected and correlated with analyte concentration as explicitly taught by Taylor et al (page 24, lines 3-11).

Response to Arguments

11. Applicant's arguments filed August 10 2006 have been fully considered and are discussed below.

A. Applicant's arguments on page 10 of the Remarks with respect to the rejections of claims 1-2 as anticipated by the Sigma Catalog have been fully considered but are moot in view of the new ground(s) of rejection necessitated by the amendments to claim 1.

B. Applicant argues on page 11 of the Remarks that the device of Schembri creates mixing bubbles using heat sources rather than fracturing bubbles. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, Schembri teaches mechanical sources for forming bubbles on the inner surfaces of the substrate (column 5, lines 18-21), and that mixing is accomplished via movement of the bubbles (column 5, lines 50-56). Thus, Schembri et al clearly establishes the utility of bubbles for use in mixing reactants within a hybridization chamber.

Applicant further argues on page 11 of the Remarks that the device of Chung et al comprising baffles is a flow-through reactor rather than a mixer, and is unconcerned with mixing. Applicant further argues on pages 11-12 of the Remarks that the purpose of the baffles is to provide a surface for the immobilization of a sorbtive material.

However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

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distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the baffles of Chung et al extend laterally into the chamber by spanning the substrate (paragraph 0052) and have a thickness that extends laterally into the chamber (Figure 5). The baffles also have sharp edges (i.e., the corners of the baffles; Figure 5). Therefore, the baffles of Chung et al meet the structural requirements of bubble-fracturing elements that extend laterally in the chamber, defined on page 9 of the instant Specification as structures that extend into the reaction chamber (e.g., span a substrate as taught by Chung et al; paragraph 0052), and have sharp edges (e.g., the corners of the baffles as taught by Chung et al; Figure 5).

In addition, in order for a reaction to occur, mixing of the reactive components must occur. Chung et al specifically state that the baffles facilitate operation of the reactor (paragraph 0048), which is interpreted to mean that the reaction between the species within the device is facilitated by the baffles. Therefore, mixing of reactive components (e.g., nucleic acid analytes and the immobilized reactive moieties) does occur within the baffled chamber of Chung et al.

Further, while Chung et al teach the sorbive material is typically and preferably on the baffles (paragraph 0056), the baffles are not required to have the sorbive material thereon. Therefore, a single exemplary embodiment of the teachings of Chung et al comprises immobilized sorbive material in the upper surface of substrate 20 within aperture 21 of Figure 4 (paragraph 56) with baffles (e.g., 23a) lacking sorbive material. The sorbive material of Chung et al is specifically for separating nucleic acids (paragraph 0057), and is therefore analogous to an array of oligonucleotides, which are typically immobilized and used to separate a specific nucleic acid analyte by hybridization.

Thus, the nexus between the device of Schembri and the device of Chung et al is established. Both devices bind (i.e., adsorb) nucleic acids using immobilized materials and require mixing of the analyte with the immobilized reactive moieties. Because Chung et al teach that the baffles facilitate the operation of the device, which is used to promote a reaction between

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immobilized reactive moieties and a target nucleic acid in the chamber (paragraph 0048), the ordinary artisan would have been motivated to modify the device of Schembri with the baffles of Chung et al to facilitate the desired reaction.

In addition, response to applicant's argument that the baffles of Chung et al are not used to fracture bubbles, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

C. Applicant argues on page 12 of the Remarks that the device of Chung et al is not intended to be manipulated. However, Applicant has clearly indicated an intended use of the apparatus. The courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in Applicant's arguments (e.g., manipulating the device, or the even fracturing of bubbles) fail to define additional structural elements to the device that are not taught by Schembri in view of Chung et al. Because the structural elements of the claims are taught by Schembri in view of Chung et al, the claims are obvious over Schembri in view of Chung et al. See MPEP § 2114.

D. Applicant argues on page 12 of the Remarks that no prima facie case for combining a reactor for separating a component from a liquid solution as taught by Chung et al with a device for reacting a liquid containing device that forms bubbles and uses thermocapillary action for moving the bubbles. Applicant further argues on pages 13-14 that there is no reasonable showing.

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However, as stated above, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. Movement of the device to fracture bubbles does not define the structure of the device unless structural limitations regarding the movement of said device are included in the claim. Schembri teaches an microarray hybridization device as described above, and further teaches that mixing is accomplished via movement of the bubbles (column 5, lines 50-56), thereby establishing the utility of the bubbles in mixing a nucleic acid target with the immobilized reactive moieties. Chung et al teach a reaction chamber having baffles, wherein the baffles facilitate use of the reactor (paragraph 0048). Because Schembri in view of Chung et al teach all of the structural limitations of the claims, and because Chung et al teach the baffles facilitate use of the reactor, the ordinary artisan would have been motivated to modify the device of Schembri et al with the baffles of Chung et al.

E. Applicant argues on page 15 of the Remarks that the examiner's conclusion of obviousness with respect to the teachings of del Valle P et al is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Chung et al teach that baffles aid in the reaction of target analytes with reactive moieties. Del Valle P et al teach that triangular baffles offer optimum regulation of reaction conditions (Abstract). The ordinary artisan would have been motivated to modify the baffles of Chung et al by making a triangularly shaped baffle as taught by del Valle P et al with a reasonable expectation of successfully optimizing reaction conditions (Abstract of del Valle P et al).

F. Applicant argues on page 15 of the Remarks that neither Bedingham et al nor Taylor et al teach bubble-fracturing elements with no further comment. The argument has been considered but is moot because these references were not used for the bubble-fracturing

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structural limitations. As noted above, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

Conclusion

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

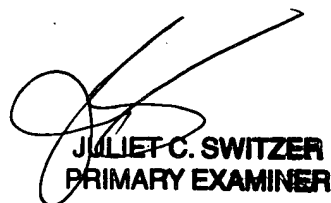
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert T. Crow
Examiner
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JULIET C. SWITZER
PRIMARY EXAMINER